

## Comparing Participants and Nonparticipants Recruited for an Effectiveness Study of Nicotine Replacement Therapy

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### ABSTRACT

**Background:** Interventions for smoking cessation have been typically evaluated on reactively recruited samples in clinical trials (efficacy trials). However, to have an impact on smoking rates in a general population, the intervention should also be evaluated with proactively recruited representative samples (effectiveness trials). **Purpose:** The characteristics of participants and two groups of nonparticipants recruited for a population-based nicotine replacement therapy study were compared. **Methods:** All members of a large New England Veterans' Administration Medical Center were contacted, and interviews were completed with 3,239 identified smokers (at least 10 cigarettes per day). At the end of the interview, all smokers were offered participation in a multiple intervention study. Of the interviewed smokers, 2,915 verbally agreed to participate in the study (90%). Of those who gave initial verbal consent, 2,054 returned the written informed consent form and became participants (70%). **Results:** The participants (full consent group) differed significantly from both nonparticipant groups—that is, the smokers who were interviewed but declined participation by active refusal (survey only group) and those who gave verbal con-

sent but passively refused participation by failing to return the written consent form (verbal consent only group). Participants were more likely to be married, younger, and female; to live with others; and to have previously used or considered using nicotine replacement therapy. The survey only group was also more likely to be in the precontemplation stage (54%), whereas the participants were more likely to be in the contemplation (46%) or preparation stage (35%). The verbal consent only group was intermediate of the other two groups in stage-of-change characteristics. **Conclusions:** An important finding was that it is possible to recruit a large proportion of a sample of identified smokers to a nicotine replacement therapy study. However, the participants are likely to differ in significant ways from those who either actively or passively decline participation.

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### INTRODUCTION

Of the people alive in the world today, 500 million are predicted to die from the use of tobacco, with an average loss of 10 years of life (1). Consequently, 5 billion years of human life will be lost to one behavior. A breakthrough in developing an intervention with even a modest impact on populations of smokers could prevent millions of premature deaths and billions of lost years of life. One of the most widely studied interventions for smoking cessation has been transdermal nicotine, the most widely used form of nicotine replacement therapy (NRT). Empirical evidence has supported the efficacy of this intervention (2–6). However, the majority of clinical trials to date have been efficacy trials—that is, studies that have involved highly select volunteer samples. A recent epidemiological study has found no evidence supporting NRT having an impact on reducing smoking rates at the popula-

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tion level (7). To support general implementation of an intervention and to resolve these conflicting results, an effectiveness trial provides critical information. An effectiveness trial has two components: recruitment and outcome. An effectiveness trial attempts to recruit a representative sample from a defined population. Two critical questions with respect to recruitment are, what proportion of the population can be recruited and how representative of the general population is the recruited sample? In this article we describe the recruitment phase of an effectiveness trial for a study of NRT combined with behavioral interventions.

### EFFECTIVENESS VERSUS EFFICACY

Clinical trials have sometimes been classified as efficacy trials or effectiveness trials (8,9). The efficacy trial relies on a volunteer sample that is randomly assigned to an intervention condition. In contrast, the effectiveness trial attempts to recruit a large representative proportion of a target population, which is similarly randomly assigned to intervention condition. Efficacy and effectiveness trials correspond to specific National Heart, Lung, and Blood Institute and National Cancer Institute research phases (10), where the efficacy trial is a Phase 3 trial and the effectiveness trial is a Phase 4 trial. For a smoking cessation treatment to be viewed as useful, it is necessary to go beyond demonstrating that the intervention is *efficacious*. It is also necessary to show that the intervention is *effective*.

One of the advantages of an effectiveness trial is that the impact of an intervention (11–13) can be estimated. Population impacts of cancer prevention programs are defined as the recruitment rate times the efficacy rate. Producing high impacts begins with recruiting high percentages of eligible populations. For example, if 80% of the population can be recruited for an intervention that has an efficacy rate of .10, the impact of the intervention will be four times larger than an intervention that has an efficacy rate of .40 but recruits only 5% of the population.

The most common approach employed for recruitment in efficacy trials has been a reactive approach; that is, individuals are informed about the availability of an intervention program and must initiate contact to participate. This produces a volunteer sample of smokers who are typically highly motivated to quit and who are likely to be compliant with the treatment protocol. Volunteer samples are also more likely to be female, White, and well educated (13). In contrast, effectiveness trials typically rely on a proactive recruitment approach; that is, individuals are contacted directly, and the services are offered to them. The samples have been more likely to reflect the general population. Two recent smoking cessation effectiveness studies (14,15) achieved recruitment rates of 82% and 85%, and the samples were demographically similar to the defined population. In contrast, efficacy studies typically recruit 1% to 5% of the population at best (16).

Beyond demonstrating the potential impact of an intervention, effectiveness trials increase the scientific community's confidence in the generalizability of the results. Interventions are often less efficacious in effectiveness trials than in efficacy trials. Several reasons might explain this result. Effectiveness trials evaluate treatments in the settings in which they are applied, whereas efficacy trials employ optimal conditions. The imple-

mentation in a real-world setting must employ available personnel rather than personnel hired especially for the study. Some part of the intervention costs may have to be borne by the participants. However, the most important issue has been the requirement to use a representative sample in the effectiveness trial. Beyond demographic differences for the sample, the intervention may only be appropriate for a small proportion of the population, and the volunteers might be much more motivated to participate in the intervention than the general population. Because the nature of the intervention may affect recruitment and retention, the effectiveness trial requires the researcher to evaluate the appropriateness of the intervention to all potential participants.

### EFFECTIVENESS STUDIES FOR SMOKING CESSATION

One recent development in smoking cessation intervention research is the increasing focus on large population-based smoking cessation trials that use a proactive recruitment strategy. However, only limited information on sample differences between nonparticipants and participants recruited using different recruitment strategies has been published. Data have been often difficult to obtain because of subject noncooperation.

A recent study (17) compared the differences in reach, enrollment, and retention between two methods of recruiting samples for a worksite intervention study. One method involved proactive recruitment, and the other employed the more traditional reactive recruitment. Proactive procedures recruited a far larger percentage of employees than that of the reactive procedures (74.5% vs. 24.4%) but significantly lower rates of enrollment (54% vs. 78%) and retention (54% vs. 70%). The proactive methods also recruited a more diverse and more high-risk sample.

A second study (18) compared a group of African Americans who were interested in participating and who returned for randomization ( $n = 500$ ) with a group of African Americans who were interested in participating but did not return for randomization ( $n = 287$ ). Members of the group who failed to return were younger, less ready to quit, and proactively recruited; they lacked a regular source of health care, expected to be smoking in 6 months, attended church less frequently, and had lower literacy.

A third, large smoking cessation study that used a recruitment strategy similar to that of this study (1a) compared the characteristics of nonparticipants to participants. Individuals were proactively recruited using random-digit-dialing methodology to answer a "health survey." People who were identified as smokers were then recruited to take part in similar surveys every 6 months and possibly receive materials about smoking through the mail. Of the 4,295 respondents to the baseline survey, 3.5% ( $n = 151$ ) refused to give consent and home addresses for future study participation.

Nonparticipants were surprisingly similar to participants on both demographic and smoking characteristics but differed significantly on eight key constructs from the Transtheoretical Model (TTM). There was only one significant difference on the seven demographic variables. The nonparticipants were older than the participants ( $M = 46.3$  vs.  $M = 40.7$ ). No significant dif-



ferences were found between participants and nonparticipants on seven traditional smoking behavior items.

With respect to stage of change, a larger proportion of nonparticipants were in the precontemplation stage (54.3% vs. 42.1%) and a smaller proportion in the preparation stage (10.6% vs. 17.6%). Nonparticipants claimed to be less tempted on the Situational Temptation subscales (Positive/Social, Negative/Affective, and Habit/Addictive) and had a less negative attitude toward their smoking with a lower Cons-of-Smoking score from the Decisional Balance Inventory. Compared to participants, nonparticipants were making less use of 4 of the 10 processes of change. These 4 underutilized processes were all experiential processes that facilitated progress through the stages of change for smokers in the early stages (20).

**THIS STUDY**

The study presented here describes in detail the proactive recruitment process of a large prospective randomized controlled study for smoking cessation in an underserved population. The aims of the study were to describe the recruitment, including how large a proportion of the population was recruited, and to compare the recruited sample to the non-recruited samples. The characteristics of those who agreed to participate are contrasted with the characteristics of those who did not participate.

**METHOD**

**Procedure**

As a first step of proactive recruitment for a smoking cessation intervention study, approximately 33,962 letters were sent out to potential recruits who were listed as members of a large Northeastern U.S. Veterans' Administration Medical Center (VAMC). The letter introduced the study as a collaboration between the University of Rhode Island and the Veterans' Administration, and it informed the potential recruits about an upcoming telephone survey. Informed consent materials for the phone survey were included in the letter. Members could return a postcard (postage prepaid) to decline to be contacted for the phone survey. A total of 5,022 returned the refusal form (14.8%). Approximately 2 weeks later, all members who did not decline participation (passive consent) were screened for study eligibility via a telephone survey. A total of 4,369 could not be contacted because of nondeliverable mail or a nonworking phone number or because they were currently residing out of the country or were deceased. Seventy-five were duplicate individuals. A total of 2,011 were eliminated for health or language issues. A total of 1,429 could not be contacted in 15 attempts (answering machines, not home, etc.), and the attempt to contact was terminated. A total of 2,664 were in the calling queue when recruitment for the study was terminated. Of the 18,392 potential participants, 3,332 refused to participate in the phone survey when contacted (22.1%). The screening survey was completed on a total sample of 15,060.

The screening survey sample of 15,060 members was assessed for smoking via the telephone survey. Screening continued until the total sample size required for the study was re-

cruited. Any spouses of VAMC members who smoked were also recruited. The eligibility criteria included self-identification as a smoker who regularly smoked 10 or more cigarettes per day and therefore met the requirements for using NRT. A total of 3,239 smokers were identified as eligible and completed the full assessment during the telephone survey. Of this group, 324 participants (10%) declined any further participation in the study after completing the initial phone survey; they are defined as the survey only group. Written informed consent materials were mailed to the 2,915 participants (90%) who provided verbal informed consent during the telephone survey. Up to 15 telephone contacts were made to participants who did not return the signed informed consent within a 2-month period. Overall, 861 individuals failed to return their written informed consent after having given verbal consent during the telephone interview (verbal consent group). The remaining 2,054 smokers (63.4% of all eligible individuals) who sent back their written consent form constituted the full consent group. All information for the study was completely confidential. Figure 1 summarizes the allocation of smokers to the three groups.

After completing the survey, all eligible smokers were randomized to one of four intervention conditions. The four intervention conditions were (a) smoking cessation manuals (21); (b) manuals and NRT (2,6); (c) manuals, NRT, and an expert system tailored print intervention (22); and (d) manuals, NRT, expert system, and telecommunications (23–25). Our study discussed here reported only the baseline assessment. The results of this study cannot be affected by the subsequent interventions. Participants were blinded to their treatment conditions until they received the first intervention materials; that is, awareness of the treatment condition could not influence the readiness for study participation. However, participants were aware that several of the possible treatment conditions included NRT and that up to three follow-up assessments by telephone were scheduled over the following 20 months.

**Sample**

A total of 3,239 smokers were identified as eligible for the study. The average age was 50.9 (*SD* = 11.0), and 78.5% were

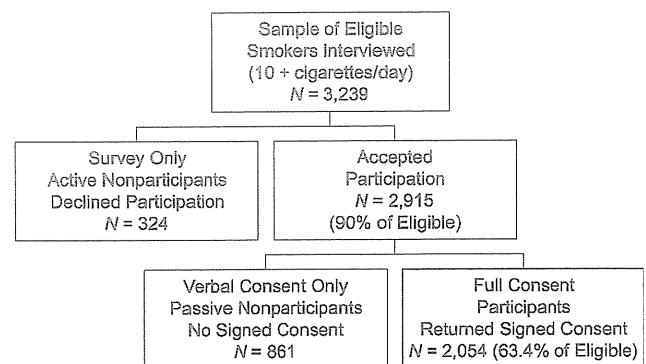


FIGURE 1 Flowchart for allocation of eligible smokers to three groups: two nonparticipant groups (survey only and verbal consent only) and the participant group (full consent).



male. The mean education level was 13.0 years ( $SD = 2.51$ ), 46.6% were currently married, and the sample was predominantly White (88.6%). For those who shared a household, 58.7% had another smoker in the house. The stage distribution included fewer smokers in precontemplation and more smokers in preparation when compared to those of other population-based samples (26,27), where distribution for five U.S. samples were approximately 40% in the precontemplation stage, 40% in the contemplation stage, and 20% in the preparation stage.

### Measures

The baseline assessment was completed on all participants in all four groups and included sociodemographic variables, smoking history, and history of NRT use. We also included the variables of the TTM for smoking cessation—that is, the stages of change; the 10 processes of change (28); the pros and cons, or decisional balance (29); and the situational temptations (30). All measures have been shown to demonstrate adequate reliability and validity in previous smoking cessation studies. Cross-sectional differences on these measures between the groups representing the stages of change have been reported elsewhere (31,32), as have longitudinal differences over a 2-year period

(20). For a recent review of the TTM applied to smoking cessation, see Spencer, Pagell, Hallion, and Adams (33).

## RESULTS

### Overview

The data analysis focused on comparing the three groups full consent ( $n = 2,054$ ), verbal consent ( $n = 861$ ), and survey only ( $n = 324$ ). All tests of statistical significance were performed at the  $\alpha = .01$  level to protect against a groupwise Type I error. The follow-up test for a significant analysis of variance was the Tukey honestly significant difference. For continuous variables, effect size was estimated by omega squared, and for discrete variables, effect size was estimated by Cramer's phi squared. The evaluation of the effect sizes follows the Cohen classification (34).

### Demographics

Table 1 presents a comparison of the three recruitment subgroups on the basic demographic variables. There was a significant gender difference,  $\chi^2(1, N = 3,239) = 26.19$ , Cramer's  $\phi^2 = 0.090$ , with disproportionately more males in the survey only

TABLE 1  
Comparison of Three Recruitment Subgroups on Demographic Variables

Variable and Category	Recruitment Subgroup			Total Sample <sup>d</sup>
	Full Consent <sup>a</sup>	Verbal Consent <sup>b</sup>	Survey Only <sup>c</sup>	
Gender				
Male (%)	77.0	78.2	89.5	78.5
Education in years ( $M$ )	13.1	12.7	13.1	13.0
Age in years ( $M$ )	50.5	50.8	54.4	50.9
Race				
White (%)	89.4	86.8	87.8	88.6
Black (%)	5.1	7.2	6.3	5.7
Asian (%)	0.1	0.1	0.0	0.1
Native American (%)	1.6	1.4	1.4	1.5
Other (%)	3.8	4.5	4.5	4.0
Household status				
Married (%)	48.2	44.7	40.0	46.6
Living with partner (%)	10.3	10.8	5.3	10.1
Not married (%)	13.8	14.4	21.8	14.6
Separated (%)	5.3	5.4	6.7	5.4
Divorced (%)	18.9	19.7	21.3	19.3
Widowed (%)	2.3	5.0	4.9	4.1
Number in house				
One (%)	21.5	23.9	33.8	23.4
Two or more (%)	78.5	76.1	66.3	76.6
Other smoker in house				
No (%)	42.4	35.6	53.4	41.3
Yes (%)	57.6	64.4	46.6	58.7
Stage				
Precontemplation (%)	18.8	34.4	53.9	26.4
Contemplation (%)	46.0	41.0	25.2	42.6
Preparation (%)	35.2	24.5	20.8	31.0

Note. There are significant differences between the groups at the  $\alpha = .01$  level.

<sup>a</sup> $n = 2,054$ . <sup>b</sup> $n = 861$ . <sup>c</sup> $n = 324$ . <sup>d</sup> $N = 3,239$ .



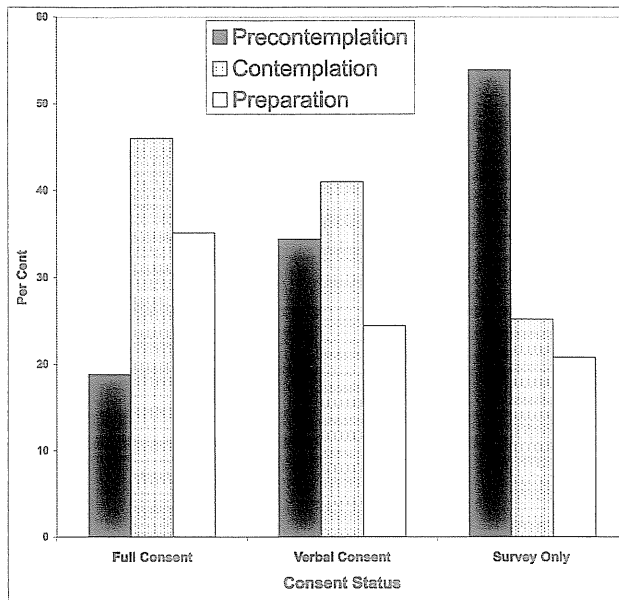


FIGURE 2 Distribution of stage of change by recruitment group.

group. There was a significant difference between the groups with respect to mean education level,  $F(2, 3128) = 7.75$ ,  $\omega^2 = 0.004$ , with the verbal consent group having a lower average education ( $M = 12.7$ ) than that of the other two groups. There was a significant difference between the groups with respect to mean age,  $F(2, 3111) = 12.82$ ,  $\omega^2 = 0.008$ , with the survey only group having a higher average age ( $M = 54.4$ ) than that of the other two groups. No differences between the groups could be identified with respect to race,  $\chi^2(8, N = 3,121) = 6.49$ . The effect size for gender was moderate. For all other differences, the effect sizes were small.

There was a significant difference in marital status,  $\chi^2(10, N = 3,133) = 23.28$ , Cramer's  $\phi^2 = 0.086$ . More participants in the full consent and verbal consent groups were married or living with a partner compared to those in the survey only group. In a related variable, there was a significant difference for the number of other persons living in the same household,  $\chi^2(2, N = 3,133) = 12.79$ , Cramer's  $\phi^2 = 0.116$ , with a greater proportion of participants in the survey only group living alone (33.8%). For those with more than one person in the household, the survey only group had a significantly higher proportion of non-smokers (53.4%) in the house,  $\chi^2(2, N = 2,385) = 18.32$ , Cramer's  $\phi^2 = 0.088$ . All effect sizes were moderate.

There was a significant difference for the distribution across the stages of change,  $\chi^2(4, N = 3,231) = 218.58$ , Cramer's  $\phi^2 = 0.26$ . In the survey only group, the majority was in the precontemplation stage (53.8%); in the verbal consent group, the respective proportion was 34.4%; and in the full consent group, it was the lowest, with 18.8% (see Figure 2). The effect size was large.

### Smoking History

Table 2 presents a comparison of the three recruitment groups on smoking history variables. There were no significant differences for the majority of the smoking history variables, including the number of cigarettes per day,  $F(2, 3236) = 0.45$ ; the

number of quit attempts in the last 3 months,  $F(2, 3213) = 2.10$ ; the number of days without smoking during the last quit attempt,  $F(2, 3201) = 1.98$ ; and the number of days without smoking in the last year,  $F(2, 3190) = 1.24$ . Participants in the survey only group reported the longest average time until their first cigarette ( $M = 47.9$  min),  $F(2, 3167) = 3.51$ ,  $\omega^2 = 0.002$ , and significantly fewer quit attempts in the previous year ( $M = 1.7$ ),  $F(2, 3201) = 11.16$ ,  $\omega^2 = 0.007$ . However, these differences involved only small effect sizes.

### NRT Use

Because a primary focus of the study was NRT, past utilization of NRT was investigated. Table 2 presents the summary statistics for the three groups. There were significant differences between the three groups with respect to previous utilization,  $\chi^2(2, N = 3,181) = 44.79$ , Cramer's  $\phi^2 = 0.13$ . The full consent group had the highest level of previous use of NRT (48.9%), whereas the use rate was lower in the verbal consent group (38.3%) and the lowest in the survey only group (30.3%). Among users, the NRT compliance, indicated by use for the recommended time, was not statistically different across the three groups,  $\chi^2(2, N = 1,381) = 7.75$ . There were significant between-group differences with respect to NRT use in the last year among users,  $\chi^2(2, N = 1,412) = 12.36$ , Cramer's  $\phi^2 = 0.094$ , with use being the highest for the full consent group and the lowest for the survey only group. Among participants who had not previously used NRT, only 28% of the participants in the survey only group had ever considered using NRT, compared to 69% in the full consent group,  $\chi^2(2, N = 1,765) = 141.64$ , Cramer's  $\phi^2 = 0.28$ . With regard to those who had ever used NRT and had ever considering using NRT, the effect sizes were large; with respect to NRT use in the last year, the effect size was moderate.

### Cognitive-Behavioral Variables

Table 3 presents a comparison of the three recruitment groups on cognitive-behavioral variables integral to the TTM. The TTM has three dimensions (35,36). Dimension 1 includes the temporal, or evolutionary, variables represented by the stages of change (see demographics mentioned earlier). The second dimension is the dependent, or intermediate, variables represented by the decisional balance, the situational temptations, and the behavioral variables described in the smoking history section. The third dimension is the independent variables, represented by the processes of change.

On Dimension 2, for the Decisional Balance Inventory, there were no significant group differences for the pros of smoking,  $F(2, 3053) = 0.584$ . There was a significant difference between groups for the cons of smoking,  $F(2, 3056) = 21.34$ ,  $\omega^2 = 0.014$ . Participants in the survey only group weighed the cons significantly lower than participants in the other two groups. For the Situational Temptations Inventory, there was a significant difference between the three recruitment groups on the Negative/Affective scale,  $F(2, 3096) = 14.11$ ,  $\omega^2 = 0.008$ , indicating that the temptation to smoke in these situations was the highest for participants in the full consent group and the lowest for participants in the survey only group. No significant group differ-



TABLE 2  
Comparison of Three Recruitment Subgroups on Nicotine Replacement and Smoking History Variables

Variable	Recruitment Subgroup			Total Sample <sup>d</sup>
	Full Consent <sup>a</sup>	Verbal Consent <sup>b</sup>	Survey Only <sup>c</sup>	
Part I. Smoking history and behavior				
Cigarettes per day				
<i>M</i>	24.5	25.0	24.7	24.6
<i>SD</i>	12.5	14.6	13.2	13.2
Quits in last 3 months				
<i>M</i>	1.3	1.1	1.1	1.2
<i>SD</i>	2.1	2.1	2.2	2.1
Quits in last 12 months <sup>e</sup>				
<i>M</i>	2.5	2.2	1.7	2.3
<i>SD</i>	3.0	3.0	2.7	3.0
Days without smoking/Last quit				
<i>M</i>	334.9	299.7	269.6	319.2
<i>SD</i>	654.8	613.0	563.3	635.7
Days without smoking (last year)				
<i>M</i>	15.3	12.9	13.7	14.5
<i>SD</i>	40.3	35.4	41.1	39.1
Minutes until first cigarette <sup>e</sup>				
<i>M</i>	35.3	39.2	47.9	37.4
<i>SD</i>	66.0	83.9	114.8	76.4
Part II. NRT utilization				
Ever use NRT? <sup>e</sup>				
Yes	48.9	38.3	30.3	43.7
No	51.1	61.7	69.1	54.5
(If yes) Use recommended time?				
Yes	40.4	35.7	52.5	40.0
No	59.6	64.3	47.5	60.0
(If yes) Use in last year? <sup>e</sup>				
Yes	45.7	36.0	33.7	42.7
No	54.3	64.0	66.3	57.3
(If no) Ever considered using? <sup>e</sup>				
Yes	68.6	47.3	28.1	58.0
No	31.4	52.7	71.9	42.0

Note. NRT = nicotine replacement therapy.

<sup>a</sup>*n* = 2,054. <sup>b</sup>*n* = 861. <sup>c</sup>*n* = 324. <sup>d</sup>*N* = 3,239. <sup>e</sup>Significant differences between the groups at the  $\alpha = .01$  level.

ences were found for the Positive/Social scale,  $F(2, 3058) = 1.75$ , or the Habit/Addictive scale,  $F(2, 3038) = 0.33$ , of the Situational Temptations Inventory. The effect size for the two significant comparisons was small.

On Dimension 3, for the Processes of Change Inventory, there were significant differences on 8 of the 10 processes scales. The three recruitment groups differed from one another on all 5 of the experiential processes of change: Consciousness Raising,  $F(2, 2316) = 33.96$ ,  $\omega^2 = 0.027$ ; Environmental Reevaluation,  $F(2, 2312) = 6.46$ ,  $\omega^2 = 0.004$ ; Self-Reevaluation,  $F(2, 2319) = 32.49$ ,  $\omega^2 = 0.026$ ; Social Liberation,  $F(2, 2291) = 9.38$ ,  $\omega^2 = 0.006$ ; and Dramatic Relief,  $F(2, 2312) = 13.40$ ,  $\omega^2 = 0.010$ . A similar pattern occurred across all 5 experiential processes: Process use was the highest for the full consent group and the lowest for the survey only group (see Table 3). Significant differences between the three recruitment groups were also

found for three of the behavioral processes scales: Helping Relationship,  $F(2, 2295) = 5.79$ ,  $\omega^2 = 0.003$ ; Self-Liberation,  $F(2, 2310) = 10.19$ ,  $\omega^2 = 0.007$ ; and Counterconditioning,  $F(2, 2295) = 4.82$ ,  $\omega^2 = 0.003$ . Once again, the same pattern of differences was observed, with process use the highest for the full consent group and the lowest for the survey only group, but the effect sizes were generally smaller. There was no significant group difference for reinforcement management,  $F(2, 2300) = 2.04$ , and stimulus control,  $F(2, 2311) = 3.62$ . All effect sizes for the processes of change were small.

#### Interactions Between Stage and Recruitment

Because the stage of change variable had the largest effect size, an additional analysis was performed to determine if any of the observed differences between the recruitment subgroups were differentially affected by stage of change. Again, all tests



TABLE 3  
Comparison of Three Recruitment Subgroups on the Processes of Change, Decisional Balance, and Situational Temptations Scales

Variable	Recruitment Subgroup			
	Full Consent <sup>a</sup>	Verbal Consent <sup>b</sup>	Survey Only <sup>c</sup>	Total Sample <sup>d</sup>
Part I. Decisional balance and situational temptations (Dimension 2)				
Decisional balance: Pros				
<i>M</i>	11.9	11.8	12.1	11.9
<i>SD</i>	3.8	4.0	4.2	3.9
Decisional balance: Cons <sup>e</sup>				
<i>M</i>	14.6	14.0	12.9	14.4
<i>SD</i>	3.9	4.0	4.5	4.0
Temptations: Positive/Social				
<i>M</i>	10.9	10.9	10.5	10.8
<i>SD</i>	2.8	2.8	3.1	2.8
Temptations: Habit/Addictive				
<i>M</i>	9.7	9.6	9.6	9.6
<i>SD</i>	2.9	3.1	3.3	3.0
Temptations: Negative/Affective <sup>e</sup>				
<i>M</i>	11.8	11.4	10.7	11.6
<i>SD</i>	3.0	3.3	3.3	3.1
Part IIA. Experiential processes of change (Dimension 3)				
Consciousness Raising <sup>e</sup>				
<i>M</i>	6.7	6.3	5.4	6.5
<i>SD</i>	2.2	2.2	2.2	2.2
Environmental Reevaluation <sup>e</sup>				
<i>M</i>	5.5	5.4	4.7	5.4
<i>SD</i>	2.8	2.8	2.8	2.8
Self-Reevaluation <sup>e</sup>				
<i>M</i>	6.5	6.0	4.8	6.2
<i>SD</i>	2.7	2.8	2.9	2.8
Social Liberation <sup>e</sup>				
<i>M</i>	8.1	7.7	7.5	7.9
<i>SD</i>	2.0	2.1	2.4	2.1
Dramatic Relief <sup>e</sup>				
<i>M</i>	5.4	5.4	4.5	5.4
<i>SD</i>	2.4	2.4	2.3	2.4
Part IIB. Behavioral processes of change (Dimension 3)				
Helping Relationship <sup>e</sup>				
<i>M</i>	5.0	5.0	4.3	4.9
<i>SD</i>	2.8	2.7	2.7	2.8
Self-Liberation <sup>e</sup>				
<i>M</i>	6.4	6.1	5.7	6.3
<i>SD</i>	2.4	2.5	2.7	2.5
Counterconditioning <sup>e</sup>				
<i>M</i>	4.7	4.8	4.3	4.7
<i>SD</i>	2.0	2.0	1.9	2.0
Reinforcement Management				
<i>M</i>	4.1	4.1	3.7	4.1
<i>SD</i>	2.4	2.4	2.5	2.4
Stimulus Control				
<i>M</i>	3.4	3.2	3.0	3.3
<i>SD</i>	1.9	2.0	1.7	1.9

<sup>a</sup>*n* = 2,054. <sup>b</sup>*n* = 861. <sup>c</sup>*n* = 324. <sup>d</sup>*N* = 3,239. <sup>e</sup>Significant differences between the groups at the  $\alpha = .01$  level.



of statistical significance were performed at the  $\alpha = .01$  level to protect against a groupwise Type I error.

*Demographics.* There were no significant differences for education, age, race, and marital status. There was a significant difference for gender. Overall, there were disproportionately more males in the survey only group. This was more exaggerated in the contemplation (93.8%) and preparation (92.4%) groups than in the precontemplation group (86.0%). There was a significant difference for number of people living in the same household. Overall, there were disproportionately more participants living alone in the survey only group. This was more exaggerated in the contemplation (41.1%) and preparation (38.1%) stages than in the precontemplation stage (28.6%). There was also a significant difference for whether there was another smoker in the household. Overall, there were disproportionately more nonsmokers in the households for the survey only group. This was more exaggerated for the precontemplation group (55.3%) than for either the contemplation (51.5%) or preparation group (53.8%).

*Smoking history.* There were no significant differences involving number of cigarettes per day, number of quit attempts in the past 3 months, number of days without smoking, number of days without smoking in last year, and number of cigarettes per day. There was a significant effect for minutes to first cigarette. Overall, the survey only group had the longest time to the first cigarette. This was more exaggerated in the precontemplation stage ( $M = 54.0$ ) than in the contemplation ( $M = 36.8$ ) and preparation stages ( $M = 48.5$ ).

*NRT use.* There were no significant effects involving whether the groups ever used NRT, used NRT for the recommended time, and used NRT in the last year. There was a significant effect for whether they had ever considered using NRT. Overall, there were disproportionately more members of the full consent group who had considered using NRT. This was the more exaggerated in the contemplation (75.6%) and preparation (78.4%) groups than in the precontemplation group (44.2%).

*Cognitive-behavioral variables.* There were no significant differences for the two scales of the Decisional Balance Inventory and the three scales of the Situational Temptations Inventory. There were no significant differences for the following eight scales from the Processes of Change Inventory: Environmental Reevaluation, Social Liberation, Dramatic Relief, Helping Relationship, Self-Liberation, Counterconditioning, Reinforcement Management, and Stimulus Control. There was a significant difference for Consciousness Raising. There was an overall tendency for the survey only group to use this process the least. This was more exaggerated in the precontemplation stage ( $M = 4.6$ ) than in the contemplation ( $M = 6.1$ ) or preparation ( $M = 6.5$ ) stages. There was also a significant difference for Self-Reevaluation. Overall, the survey only group used this process the least. This was more exaggerated in the precontem-

plation stage ( $M = 3.3$ ) than in the contemplation ( $M = 6.0$ ) or preparation stages ( $M = 6.6$ ).

## DISCUSSION

Interventions for smoking cessation have been typically evaluated on reactively recruited samples in clinical trials (efficacy trials). However, to have an impact on smoking rates in a general population, the intervention should also be evaluated with proactively recruited representative samples (effectiveness trials). The attempt to recruit a representative sample can be limited by the potential participants' refusal to participate. There are two aspects of the recruited sample that need to be evaluated: (a) the overall proportion of the potential sample that the study is able to recruit (and retain) and (b) the differences between those who accept participation and those who decline. Unfortunately, there is frequently only limited or no information available about the nonparticipants. For this study, the recruitment procedure produced an opportunity to compare participants with two different groups of nonparticipants.

The first important finding is that it is possible to recruit a high proportion of the identified smokers to participate in a cessation study that involves NRT. The overall recruitment rate was 63.4% of the identified smokers. This is somewhat lower than the participation rates that have been reported by our research group employing a similar proactive recruitment procedure. The most directly comparable study was an HMO-based study that recruited 85% of the eligible sample (13,14). However, the procedure employed in that study did not require the return of the signed written consent, so the more comparable recruitment figure is the 90% of the participants in this study who provided verbal consent. (Participants in the HMO study who gave verbal consent and received a written copy of the consent form that was communicated over the phone did not need to take any action on the written consent.) The calculation of the recruitment rate did not include the high proportion of those who declined to participate in the phone survey (14.8%), because their statuses were unknown. It also did not include the members of the VAMC who could not be contacted, because both their existences and smoking statuses were unknown.

The second important finding is that the smokers who declined participation were different in many ways from those who agreed to participate. The results indicate that individuals who only participated in the survey (survey only group) stood out as a special group. They were different from the other participants with respect to a number of demographic, cognitive-behavioral, and—to a lesser extent—smoking-related behavioral variables. Individuals who accepted participation verbally but failed to return the consent forms (verbal consent group) typically displayed characteristics that were somewhere between the survey only and full consent groups but more similar to those of the full consent groups.

The largest differences occurred for stage of change and NRT use. The survey only group had a much higher proportion of precontemplation stage smokers (53.9%) than did the full consent group (18.8%). Although it is not surprising that smokers in the Precontemplation stage were less likely to participate



in a study about smoking, the proportion of full consent group participants in the precontemplation stage was very low compared to that of other proactive recruitment studies that our group has performed, where the proportion is typically around 40% (26,27). The differences in stage distribution between the three groups may be the single factor that explains most of the other differences observed.

The use of NRT as a potential intervention may have highlighted the cessation characteristic of the study more than other stage-based intervention studies because it was clearly most relevant for the preparation–action transition. It may have changed the perception of potential participants of the intervention being studied from one that was stage appropriate to one that was action oriented and thus inappropriate for early-stage participants. Support for this interpretation is provided by the NRT-use questions, where almost 50% of the full consent group had previously used NRT, compared to 30.3% for the survey only group. The differences were even more striking among those who had not previously used NRT, where 68.6% of the full consent group had considered using it, compared to 28.1% of the survey only group. In the study, NRT was only provided to those smokers who were ready to use it. However, either this was not clearly communicated or the mere presence of NRT as a potential intervention resulted in early-stage smokers, particularly those who had never considered NRT, choosing to decline participation.

The survey only group differed on a number of important demographic variables. The group included a higher proportion of males, was more likely to be without a spouse or other partner, and was more likely to be living alone. The one finding that was not in the expected direction was the lower percentage of other smokers in the house for the survey only group.

The three groups differed on the cognitive-behavioral measures, with the survey only group showing the least use of the processes of change and the lowest perception of the cons of smoking. These differences were consistent with the stage differences between the groups. An unusual finding was that the survey only group demonstrated the lowest temptation to smoke in negative affect situations.

There was some overlap between the finding of this study and the most comparable available study (18). Recruitment method and access to health care could not be compared since they were constants for all participants in this study. Nonparticipants in both studies were less ready to quit, had a lower education level, and planned to be smoking in 6 months. Age was in the opposite direction from our study, but our sample was very unusual with respect to this variable.

A unique aspect of our study was the use of a VAMC population. The study reported in Fava, Velicer, and Prochaska (31) employed the proactive recruitment procedure to recruit a random-digit-dial sample. The VAMC sample was older ( $M = 50.9$  years vs. 40.7), more educated (13.0 years vs. 12.7), predominantly male (78.5% vs. 40.7%), less likely to be married (46.6% vs. 53.5%), and more likely to be in the Preparation stage (31.0% vs. 17.6%). The VAMC system was also more oriented to providing services at a single central location than were other health care providers. Some of the results of this study may have

been influenced by the unique characteristics of the VAMC sample and the VAMC health care system.

The use of the VAMC sample may have also detracted from our ability to make any firm conclusions about the representativeness of the sample. First, the proportion that returned the refusal form (14.8%) was extremely high compared to that of other studies that employed the same proactive recruitment procedure, where the proportion refusing participation before the telephone survey has been typically less than 5%. This might reflect the fact that some proportion of the VAMC sample employed other health care organizations as their primary health care provider. Second, the proportion of potential participants who could not be contacted (22.3%; individuals with nondeliverable mail or a nonworking phone number, people currently residing out of the country, deceased individuals, duplicate listings, or people eliminated for health or language issues) was unusually high and may have reflected the degree to which the VAMC patient list accurately reflected the current membership. The proportion may also have reflected the high average age of the VAMC sample, resulting in a higher proportion that was deceased or incapacitated. Replication of this study within another health care organization would help to determine if some of these recruitment issues were unique to a VAMC population.

This study employed the TTM as the basic conceptual model to guide the selection of variables. A more detailed description of the model can be found elsewhere (35,36). Although the model has received extensive empirical support in the literature, there have been several recent criticisms of the model. One criticism (37–39) has been that the TTM is a descriptive but not predictive theory. On one level, this would represent an indictment of most psychosocial theories because the TTM, as the name implies, incorporates many of the major constructs from all of the leading theoretical models. However, a majority of published studies have supported the predictive ability of the TTM. In particular, a recent secondary data analysis (40) of five smoking cessation clinical trials found that stage alone was one of the best predictors of outcome at 24 months, demonstrating a large effect size (Cramer's  $\phi^2 = 0.167$ ). In other studies, the model was successful in predicting the actual effect sizes for multiple predictions (41). A detailed analysis of these critical studies was presented in a paper applying a hierarchy of criteria for evaluating theories of health behavior change to TTM (42). A recent article (43) that was critical of the TTM is a narrative review (as opposed to a meta-analytic review) that was heavily criticized by the online editorial comments for, among other things, an incomplete review of the available literature, the failure to weigh the studies by scientific quality, and conclusions that were inconsistent with the studies reviewed. Fortunately, a more comprehensive and balanced recent review is available (33).

## CONCLUSIONS

This study demonstrates that it is possible to recruit a high proportion of the identified smokers to participate in a smoking cessation study that includes NRT. However, the recruitment procedure resulted in a biased sample, with smokers in the early



stages less likely to agree to participate. Alternative recruitment procedures should be developed to increase participation rates of these smokers. For example, the emphasis on the potential use of NRT at the initial stages of the recruitment process may have alienated the early stage smokers because it was clearly a cessation aid. Following the concept of preparing smokers for patch use, a two-step recruitment process might be employed for early stage smokers. The first step could be recruitment to a smoking study rather than a smoking cessation study. The second step could focus on informed consent for NRT when NRT use is appropriate—that is, when the smoker has advanced to a later stage. The combination of membership in an early stage of change and social isolation presents a picture of a smoker who is unlikely to progress without assistance. It is important that recruitment procedures, including informed consent procedures, do not systematically exclude a segment of the population of smokers that need intervention services.

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